

# EXHIBIT 19

VIA EFS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Declan Walsh *et al.*

Conf. No.: 6857 : Group Art Unit: 2876  
Appln. No.: 14/699,567 : Examiner: Daniel A. Hess  
Filing Date: April 29, 2015 : Attorney Docket No.: 026723-5043-US-06  
Title: DOSE COUNTER FOR INHALER AND METHOD FOR COUNTING DOSES

**REQUEST FOR RECONSIDERATION**

The following Response is submitted in response to the non-final Office Action dated May 22, 2017 (Paper no. 20170517) No extension of time fee is believed to be due as this Response is being timely filed on or before the initial deadline of August 22, 2017.

Except for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. **50-0310** (Billing No. 026723-5043-US-06).

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**LISTING OF THE CLAIMS**

The claims currently pending in this application:

1. (Previously Presented) A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

    a ratchet wheel having a plurality of circumferentially spaced teeth,

    an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,

    a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth,

    a dosage indicator associated with the count pawl,

    wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth; and

    wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count.

2. (Previously Presented) A dose counter as claimed in Claim 1 in which the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations.

3. (Cancelled)

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4. (Previously Presented) A dose counter as claimed in Claim 1 wherein the dosage indicator includes a tape with incremental dose indicia located thereon, the tape being positioned on a tape stock bobbin and arranged to unwind therefrom.

5. (Previously Presented) A dose counter as claimed in Claim 1 in which the actuator and ratchet wheel are arranged to provide a start configuration at which the actuator is spaced from the ratchet wheel, and an end configuration at which the actuator disengages from the ratchet wheel during the canister fire sequence.

6. (Previously Presented) A dose counter as claimed in claim 5 in which:

- (a) the actuator is arranged to be located about 1.5 to 2.0 mm from its location in the fire configuration when in the start configuration;
- (b) the actuator is arranged to be located about 1.0 to 1.2 mm from its location in the fire configuration when in the reset configuration; or
- (c) the actuator is arranged to be located about 1.1 to 1.3 mm from its location in the fire configuration when in the end configuration.

7. (Previously Presented) A dose counter as claimed in Claim 5 in which the body includes a formation for forcing the actuator to disengage from the ratchet wheel when the actuator is moved past the end configuration.

8. (Previously Presented) A dose counter as claimed in claim 1, wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion therebetween.

9. (Previously Presented) A dose counter as claimed in Claim 8 in which the actuator and ratchet wheel are arranged to provide a start configuration at which the actuator is spaced from the ratchet wheel, and an end configuration at which the actuator disengages from the ratchet wheel during the canister fire sequence and in which the count pawl is substantially fixedly mounted on the body and in which the count pawl is arranged to be capable of repeatedly engaging the teeth of the ratchet wheel in anti-back drive interlock configurations as the dose

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counter is operated, the count pawl being positioned so that the ratchet wheel is halfway, or substantially halfway, moved from one anti-back interlock configuration to the next when the actuator and ratchet wheel are in the end configuration thereof.

10. (Previously Presented) An inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed in claim 1.

11. (Previously Presented) An inhaler as claimed in Claim 10 in which the body includes a canister-receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator.

12. (Previously Presented) The dose counter as claimed in Claim 4, wherein the incremental dose indicia on the tape is in the form of even numbers and the body includes a dose marker that points to a location either at one of the even numbers or between two adjacent even numbers.

13. (Previously Presented) A dose counter as claimed in claim 5 in which:

(a) the actuator is arranged to be located about 1.5 to 2.0 mm from its location in the fire configuration when in the start configuration;

(b) the actuator is arranged to be located about 1.0 to 1.2 mm from its location in the fire configuration when in the reset configuration; and

(c) the actuator is arranged to be located about 1.1 to 1.3 mm from its location in the fire configuration when in the end configuration.

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**REMARKS**

1. Claims 1-2 and 4-13 are currently pending in the application. None of the claims have been amended. Thus, no new matter has been added.

***Claim Rejections – 35 U.S.C. § 102***

2. The Examiner rejected claims 1, 4, and 10-11 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,446,627 to Bowman *et al.* (hereinafter “Bowman”).

Claim 1 recites:

A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

a ratchet wheel having a plurality of circumferentially spaced teeth,

an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,

a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth,

a dosage indicator associated with the count pawl,

wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth; and

wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count.

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Bowman does not disclose each and every element of claim 1. Bowman describes an inhaler with a dose counter. Bowman states

“By controlling the position of engagement and disengagement between the drive means and the wheel, the travel required to count is precisely regulated. For maximum reliability and accuracy, the counter must only index after the metering valve has delivered its dose from the inhaler. If it counts before this, users can index the counter without receiving a dose of medicament. In extreme cases, the user could end up with a counter reading empty when the medicament reservoir is actually full. Hence, the travel from rest to the fire point can be defined as the ‘must not count’ zone.

As soon as possible after firing, the counter needs to index, the upper limit being the extent of full travel of the metering valve. This can be defined as the ‘must count’ zone. Since all assemblies have tolerances necessary for reliable production, part of the “must count” zone is required for the fire position variance and part for the full valve travel variance.”

Bowman col. 4 lines 37-54

Applicant respectfully submits that Bowman teaches that being able to index the counter without receiving a dose of medicament is undesirable and that avoiding a situation in which the counter reads empty when the reservoir is actually full should be avoided. The solution is that as soon as possible after firing, the counter must index – this is the “must count” zone.

It is first noted that there are two means of preventing reverse rotation disclosed in Bowman: a fixed pawl and a wrap spring clutch. The Examiner stated that he is only concerned with the embodiment where the anti-back-drive is a pawl (Figures 4 and 6a). Office Action page 2. However, this interpretation of Bowman appears to be the result of improper hindsight gleaned from Applicant’s own disclosure.

The Examiner interpreted “counting” in Bowman as being when the fixed pawl jumps over the ratchet wheel tooth from one interlock position to the next. This is, however, not taught by Bowman, and instead is only taught by the present application.

The Examiner also states that “it has been seen that first contact (position 1) is separated from counting (position 3) by the turn of the ratchet wheel one increment and thus positions 1 and 3 are separated by significant time and distance”. The examiner states that because firing (position 2) and counting (position 3) are close together the first contact (position 1) must be

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before firing (position 2). Office Action page 7. However, there is no support for this interpretation in Bowman.

Applicant respectfully submits that the passage in question states that “[a]s soon as possible after firing, the counter needs to index” – not count. (emphasis added) Thus, it is indexing that must be close to, but after, firing. Bowman is silent as to the movement of a fixed pawl in this context.

Furthermore, a wrapped spring clutch counter provides continuous resistance to reverse rotation of the counter. Thus, if such a counter resets before the canister is fired, the counter could be progressed without firing the canister, and in extreme cases this could lead to a counter that showed the canister to be empty when in fact it was full. This is exactly the problem that Bowman sets out to solve. Applicant respectfully submits that an interpretation of what is meant by indexing in Bowman cannot be correct if it can result in a counter described as being “an especially preferred embodiment” suffering from the very problem Bowman means to address.

In contrast to such an interpretation, the ratchet wheel of Bowman must not move until after the canister has fired to avoid the problem of the counter being moved forward without the canister firing. Applicant respectfully submits that this is the teaching of Bowman.

That indexing relates to the motion of the ratchet wheel more generally and not to the specific action of a fixed pawl is further supported by column 8, lines 13-16, of Bowman where it is explained that the spacing between the successive markings on the tape are coincident with the indexing motion of the matching wheel: i.e., it is the ratchet wheel that moves/indexes and it is movement/indexing of the ratchet wheel that should be avoided before dispensing the dose of medicament.

This interpretation of Bowman is further supported by the claims in Bowman. Claim 1 of Bowman refers to “a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise motion of the rotary gear means”. Again, avoiding indexing before the canister fires would require avoiding movement of the ratchet wheel because any movement of the ratchet wheel moves the tape.

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Figure 3 of Bowman shows a counter before the actuator is moved at all: this is clear from the lines indicating the valve travel - the top of the actuator is in line with the start of valve travel. It can also be seen that the hook element is spaced from the tooth with which it is intended to engage (i.e., the tooth protruding between the arms (352, 353)). Therefore, when the counter reaches the reset position, the actuator will already have moved a significant distance. Applicant respectfully submits that this spacing is the “must not count” zone during which canister fire occurs, which is consistent with the above analysis. Moreover, it would appear from Figure 3 that any movement of the protruding tooth will cause the next tooth to appear beyond the control surface. Therefore, if the canister did not fire until after it engaged the protruding tooth (as proposed by the examiner), the hook element could be returned to its start position, engage the next tooth and move the counter without a dose having been fired from the canister. The wheel having been held in its semi-advanced position by the wrap-spring clutch.

Figure 4 shows a conventional ratchet wheel; however, unlike Figure 3 it does not disclose where the illustrated position is relative to the canister firing. The conventional ratchet is illustrated in total isolation from the remainder of the inhaler. Accordingly, the canister could have already fired before the illustrated position was reached. Furthermore, if the Examiner does consider the illustrated ratchet wheel an accurate representation of an inhaler counter, rather than a schematic illustration of a conventional ratchet wheel, we note that the illustrated ratchet wheel is not shown in a start position because the hook is already below the tip of the tooth with which it is to engage. The hook must therefore have started in a higher position: how much higher is not shown. Again, therefore, an interpretation that the ratchet wheel should not move until after the canister fires is consistent with what is illustrated.

Figure 6(a) provides no additional direction to the skilled person beyond Figure 4. Again, it cannot be in the start position because otherwise the fixed pawl would not prevent reverse rotation. However, it is not clear how far the hook element (650) has travelled, nor when the canister fired. Thus, Bowman does not teach, suggest or describe the inhaler of claim 1.

The Applicant therefore respectfully asserts that claim 1 is allowable as written and respectfully requests reconsideration of the rejection of claim 1. Claims 4 and 10-11 depend from claim 1 and are therefore allowable for at least the same reasons that claim 1 is allowable.

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***Claim Rejections – 35 U.S.C. § 103***

3. The Examiner rejected claims 2, 5-9, and 12-13 under 35 U.S.C. § 103(a) as unpatentable over Bowman. Claims 2, 5-9, and 12-13 depend upon claim 1 and are patentable over Bowman for at least the same reason discussed above. Accordingly, Applicant respectfully requests that the rejection of claims 2, 5-9, and 12-13 be reconsidered and withdrawn.

**CONCLUSION**

4. Each and every ground of each rejection in the outstanding office action has been addressed herein. To the extent a particular argument in support of a rejection by the Examiner is not expressly addressed, that argument is moot in view of the foregoing and Applicant does not acquiesce to any such argument or the Examiner's characterization of the cited references.

In view of the foregoing remarks, Applicant respectfully submits that the present application, including claims 1-2 and 4-13, is in condition for allowance and such action is respectfully requested. Should the Examiner determine otherwise, Applicant's representatives suggest a telephone interview in order to expedite prosecution of the application.

Respectfully submitted,

Date: August 22, 2017

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